

In The United States Court of Federal Claims

No. 13-1002V
(Filed under seal: October 5, 2016)
Reissued: October 20, 2016¹

DILLON COPENHAVER and AMANDA COPENHAVER, on behalf of their deceased minor child, NICHOLAS COPENHAVER,	*
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Petitioners,	* Vaccine case; Motion for Review; Hepatitis-B vaccination; Standard of review; <i>Althen</i> ;
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v.	Failure to establish causation; Motion for Review denied.
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SECRETARY OF HEALTH AND HUMAN SERVICES,	*
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	*
Respondent.	*

OPINION

Andrew Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioners.

Claudia B. Gangi, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

SMITH, Senior Judge:

Petitioners, Dillon Copenhaver and Amanda Copenhaver, on behalf of their deceased minor child, Nicholas Copenhaver, seek review of a decision issued by Special Master Christian J. Moran denying their petition for vaccine injury compensation. Petitioners brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (2012), alleging that Nicholas died from Sudden Infant Death Syndrome (“SIDS”) that was caused by the hepatitis-B (“Hep B”), diphtheria-tetanus-acellular-pertussis (“DTaP”), inactive polio vaccine (“IPV”), and haemophilus influenza type b (“Hib”) vaccines that he received at his four month well-child visit. The Special Master denied compensation, finding that Nicholas’

¹ An unredacted version of this opinion was issued under seal on March 9, 2016. The parties were given an opportunity to propose redactions, but no such proposals were made.

SIDS was not caused by the vaccinations. *Copenhaver v. Sec'y of Health & Human Servs.*, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016) (*Copenhaver*). Petitioners now move for review of this decision. For the reasons that follow, the Court **DENIES** their motion.

I. BACKGROUND

A brief recitation of the facts provides necessary context.²

Nicholas was born on March 7, 2013. His two week and two month checkups were routine, and he received a set of vaccinations at his two-month well-child visit. After his two-month vaccines, Ms. Copenhaver stated that he had a fever that Tylenol controlled.

On July 12, 2013, Nicholas attended his four month well-child visit to the pediatrician. At that appointment, he received his Hep B, DTaP, IPV, and Hib vaccines. After receiving the July 12, 2013 vaccines, Nicholas was reportedly unsettled, restless, fussy, and lethargic, and he ran a low-grade fever. On the evening of Sunday, July 14, 2013, the Copenhavers dropped Nicholas off with his babysitter, Ms. Schoneboom. At approximately 1:00 a.m., Nicholas awoke and became fussy, so Ms. Schoneboom swaddled him in a blanket and held him up on her shoulder while she watched television. At approximately 4:00 a.m. on July 15, 2013, Ms. Schoneboom awoke to discover that Nicholas was not breathing. She attempted to resuscitate him and called 911, but efforts to revive Nicholas were unsuccessful.

A general autopsy was performed on August 13, 2013, by Karl Christopher Stacy. He referred the neuropathology to Dr. Douglas C. Miller, who performed an investigation, which revealed two problems in Nicholas' brain. The first issue was "a small malformation of one hippocampus, representing a potential cause for seizures." Petitioners' Exhibit (hereinafter "Pet. Ex.") 2 at 11. The second issue was swelling in the cerebellum. *Id.* at 10; Transcript of Proceedings, July 30-31, 2015, at 87-88, 113-17, 241 (hereinafter "Tr. ____"). Dr. Miller also noted that Nicholas did not have a defect in the arcuate nuclei,³ a brain abnormality commonly found in SIDS⁴ cases. Pet. Ex. 2 at 11; Tr. 179-81. Dr. Miller concluded that the vaccinations contributed to Nicholas' death. Alternatively, Dr. Stacy concluded that "the cause of death of this sudden unexpected death of Nicholas Copenhaver is most likely rebreathing due to sleeping situation." Pet. Ex. 2 at 2, Tr. 181-82.

² As the basic facts here have not changed significantly, the Court's recitation of the background facts here draws from the Special Master's earlier opinion in *Copenhaver*.

³ The arcuate nucleus is defined as "one of the small group of small, irregular areas of gray substance found on the ventromedial aspect of the pyramid of the medulla oblongata." *Dorland's Illustrated Medical Dictionary* 1295 (32nd ed. 2012) ("Dorland's").

⁴ Sudden Infant Death Syndrome is defined as "the sudden and unexpected death of an apparently healthy infant, typically occurring between the ages of three weeks and five months, and not explained by careful postmortem studies." *Dorland's* 1850

Petitioners filed their vaccine petition on December 19, 2013, pursuant to the Vaccine Act, and alleging that “Nicholas’ death was caused by an adverse reaction to his July 12, 2013 vaccinations.” *See* Petition at 5. Petitioners filed the expert report and curriculum vitae of Dr. Douglas C. Miller,⁵ a neuropathologist, on July 7, 2014. Petitioners filed an expert report from Dr. David Axelrod,⁶ an immunologist, on August 12, 2014. Respondent filed an expert report from Dr. Brent T Harris,⁷ a neuropathologist, on December 16, 2014. Respondent filed a second expert report from Dr. Christine McCusker,⁸ an immunologist, on December 22, 2014.

An entitlement hearing was held in Washington, DC on July 30 and 31, 2015. On May 31, 2016, Special Master Moran issued a decision denying petitioners’ claim and finding that petitioners were not entitled to compensation because they failed to provide preponderate

⁵ Dr. Miller received his medical degree from the University of Miami, School of Medicine in 1978. Curriculum Vitae of Dr. Douglas C. Miller, Pet. Ex. 14 at 1. He has a Ph.D. in physiology and biophysics from the University of Miami. *Id.* He was a resident at Massachusetts General Hospital from 1980-84, focusing in anatomic pathology and neuropathology. *Id.* Most recently he serves as a clinical professor of pathology and anatomical science at the University of Missouri, School of Medicine, and he is the program director of pathology residency. *Id.* at 3. He is an associate medical examiner for Boone, Callaway, and Greene Counties in Missouri. *Id.*

⁶ Dr. Axelrod received his medical degree from the University of Michigan Medical School in 1974. Pet. Ex. 16 at 1. He is board certified in internal medicine, rheumatology, medical laboratory immunology, and allergy and immunology. *Id.* at 3. He was an associate professor of rheumatology at the Medical College of Ohio from 1989-91. *Id.* at 2. He was an associate professor from 2007-10 at the New Jersey Medical School, and during the latter two years of that period he was the interim director of the division of allergy, immunology, and rheumatology. *Id.* From 2010-12 he was an associate professor at Oakland University. *Id.*

⁷ Dr. Harris received both his medical degree from Georgetown University School of Medicine and his Ph.D. in pharmacology from Georgetown University Graduate School in 1995. Respondent’s Exhibit (hereinafter “Resp. Ex.”) B at 2. From 2002-10, he was an assistant professor of pathology at Dartmouth Medical School. *Id.* at 3. He served as an adjunct professor of neurology at Dartmouth Medical School from 2010-13. *Id.* Since 2011 he has concurrently served as an adjunct associate professor of pathology at Howard University Medical School and as an associate professor of neurology and pathology at Georgetown University School of Medicine, and he is a member of the teaching faculty for the Pediatric Neurology Program at Children’s National Medical Center in Washington, D.C. *Id.* at 2-3.

⁸ Dr. McCusker earned a Master’s of Science at McMaster University in 1988 and a medical degree at McMaster University in Hamilton, Ontario (Canada) in 1993. Resp. Ex. D at 2. Her residency training in pediatrics was at Montreal Children’s Hospital, McGill University. *Id.* at 3. She was a clinical fellow in allergy and immunology at McGill University from 1996-99. *Id.* She served as an assistant professor of pediatric allergy and immunology from 2000-08 and has been an associate professor of the same since 2009 at Montreal Children’s Hospital and McGill University. *Id.* at 4. She is board certified in pediatrics. *Id.* at 3.

evidence that the vaccinations Nicholas received on July 12, 2013, caused his death. On June 30, 2016, petitioners filed a Motion for Review (“MFR”) of the Special Master’s decision. Respondent filed a response to petitioners’ Motion for Review (“Resp. to MFR”) on August 1, 2016. Petitioners submitted their reply in support of their Motion for Review on August 10, 2016. Argument on this motion is deemed unnecessary, and the Motion for Review is now ripe for decision.

II. DISCUSSION

Under the Vaccine Act, this Court may review a special master’s decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the Court may: “(A) uphold the findings of fact and conclusions of law..., (B) set aside any findings of fact or conclusion of law...found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law..., or, (C) remand the petition to the special master for further action in accordance with the court’s direction.” *Id.* at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an “arbitrary and capricious” standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec’y of Health & Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec’y of Health & Human Servs.*, 92 Fed. Cl. 1, 5 (2010).

Althen provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. *See generally Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). In order to prove causation-in-fact, a petitioner must

show by preponderant evidence that the vaccination brought about [petitioner’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278. In order to succeed, petitioners must provide a “reputable medical or scientific explanation” for their claim. *Id.*

Within this framework, petitioners make five numbered objections to the May 31, 2016 decision. *See* MFR at 2. First, they assert that the Special Master improperly concluded that petitioners failed to demonstrate that the Triple Risk Model should be extended to vaccination. *Id.* Second, they argue that the Special Master improperly concluded that petitioners failed to show that vaccinations caused Nicholas to die from SIDS. *Id.* Third, they assert that the Special Master improperly discredited Dr. Axelrod’s expert immunology testimony and accorded much greater weight to Dr. McCusker’s expert immunology testimony. *Id.* Fourth, they posit that the Special Master improperly allowed Dr. McCusker to testify outside of her area of expertise. *Id.* Finally, petitioners argue that the Special Master failed to apply the proper standard in determining whether petitioners met their burden of proof. *Id.*

A. Triple Risk Model

Petitioners allege that Special Master Moran improperly concluded that extending the Triple Risk Model to vaccines as an extrinsic risk factor for SIDS was unwarranted. *See* Petitioners Memorandum of Objections (hereinafter “Pet. Mem.”) at 4. The Triple Risk Model is an explanation for SIDS deaths first introduced in 1994 by James J. Filiano and Hannah C Kinney. Decision (hereinafter “Dec.”) at 3. The Triple Risk Model⁹ posits that three separate factors typically coincide in cases of SIDS. *Id.* Those factors are as follows: (1) a vulnerable time period, such as when a baby develops homeostatic control, (2) a vulnerable infant, such as one with an intrinsic defect in the brain, and (3) an external stressor.¹⁰ Dec. at 4. The vulnerable development period is typically from two months to six months of age. *Id.* The intrinsic stressor most focused on in SIDS deaths is a defect in the medulla oblongata,¹¹ which is responsible for sensing the amount of carbon dioxide in the blood. *Id.* The external stressor could be any number of things, including but not limited to sleep position, minor respiratory or gastrointestinal illnesses, fever, and over-blanketing. *Id.* None of Dr. Kinney’s articles have included vaccines as an external stressor. Tr. 16061 (Dr. Miller), 427-28 (Dr. McCusker).

Medical literature does not support the idea that vaccines have an effect on SIDS related deaths. Medical literature does, however, support the idea that SIDS deaths are often related to respiratory obstruction. The “Back-to-Sleep” campaign reduced the rate of SIDS by approximately 50 percent by encouraging parents to place their sleeping babies in the supine position. Tr. 127-28, 383. Dr. Kinney opined in an article¹² from 2009 that the supine position eliminated a number of the hazardous effects of prone sleeping, including airway compression and rebreathing of exhaled gas. Resp. Ex. J at 3. This article further expounded on SIDS risk factors, including “bed clothes that covered the head, sleeping on sofas or other soft furniture in which the infant could become wedged, a high ambient temperature in sleeping environment, soft bedding, and bed sharing. *Id.* Special Master Moran highlighted that Dr. McCusker “interprets Dr. Kinney’s work as focusing on impediments in the mechanical aspects of breathing.” Dec. at 5; Tr. 380-81.

⁹ James J. Filiano and Hannah C. Kinney, A Perspective on Neuropathology Findings in Victims of Sudden Infant Death Syndrome: The Triple-Risk Model, 65 *Biology of the Neonate* 194 (1994).

¹⁰ *Id.* at 195.

¹¹ The medulla oblongata is defined as “the truncated cone of nerve tissue continuous above with the pons and below with the spinal cord. It lies anterior to the cerebellum, and the upper part of its posterior surface forms the floor of the lower part of the fourth ventricle; it contains ascending and descending tracts, and important collections of nerve cells that deal with vital functions, such as respiration, circulation, and special senses” *Dorland’s* 1121.

¹² Hannah C. Kinney and Bradley T. Thach, The Sudden Infant Death Syndrome, 361(8) *New. Eng. J. Med.* 795 (2009).

In Vaccine Act cases, as long as the finding of fact is “based on evidence in the record that [is] not wholly implausible, [this Court is] compelled to uphold the finding as not being arbitrary or capricious.” *Porter v. Sec'y of Health & Human Servs.*, 663F.3d 1242, 1249 (Fed. Cir. 2012) (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)). Special Master Moran made a determination that respiratory obstruction was a more persuasive extrinsic factor than was vaccination. This was a plausible conclusion based on the testimony of the experts and available medical literature. As it seems to the Court that Special Master Moran’s conclusion was wholly plausible, we are compelled to uphold it as neither arbitrary nor capricious.

B. Causation

Petitioners allege that Special Master Moran improperly concluded that petitioners failed to show that vaccinations caused Nicholas to die from SIDS. MFR at 2. In making this assertion, petitioners attempt to argue that “[v]accination acts as the exact same mechanism of injury as infection does in serving as an extrinsic risk factor through cytokine¹³ expression.” Pet. Mem. at 6. They cite repeatedly to a finding from an article¹⁴ by Yasuyo Kashiwagi, which found that “no significant difference was observed in the IL-6 and TNF- α levels between the influenzas outpatients and immunization groups with febrile or non-febrile illness after vaccination.” Pet. Ex. 17 at 4. Special Master Moran considered this, but ultimately determined that this “specific provision...cannot be generalized to establish that the vaccines in this case resulted in production of a comparable amount of a different cytokine (IL-1 β) as would have resulted from an infection.” Dec. at 24.

Petitioners’ argument does comport with the *Althen* test. “*Althen* requires that petitioners must provide a ‘reputable medical or scientific explanation’ for their claim.” *Cozart v. Sec'y of Health and Human Servs.*, 126 Fed. Cl. 488, 498 (2016) (quoting *Althen*, 418 F.3d at 1278). Once a plausible theory, backed by medical or scientific support, is set forth, petitioners then must show that there is “a logical sequence of cause and effect showing that vaccination was the reason for the injury.” *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1278). Petitioners in this case have done neither. Simply citing to medical literature in which vaccinations *may* have been a factor in cytokine production does not, standing alone, lead to a conclusion that the vaccines given to Nicholas on July 12, 2013 caused an increase in cytokine production, which in turn lead to his death. There is no evidence that cytokines were even present at the time of Nicholas’ death. Petitioners’ expert, Dr.

¹³ Cytokine is defined as “a generic term for nonantibody proteins released by one cell population (e.g. primed T lymphocytes) on contact with specific antigen, which act as intercellular mediators, as in the generation of an immune response.” *Dorland’s* 466.

¹⁴ Yasuyo Kashiwagi et al., “Production of Inflammatory Cytokines in Response to Diphtheria-Pertussis-Tetanus (DPT), *Haemophilus Influenzae* Type B (Hib), and 7-Valent Pneumococcal (PCV7) Vaccines,” 10(3) *Human Vaccines & Immunotherapeutics* 677 (2014).

Miller, indicated that routine autopsies do not include testing for cytokine presence. Tr. 90. Petitioners' theory relies on the presence of cytokines. It would be completely unjustified to leap to the conclusion that cytokines caused Nicholas' death when there is a complete lack of evidence that cytokines were even present at the time of his death. As such, Special Master Moran was neither irrational nor arbitrary in his conclusion that "the evidence, taken as a whole does not support the theory that vaccinations can serve as an extrinsic risk factor by stimulating the production of cytokines that impair the brain's functioning." Dec. at 33.

C. Weight of Expert Opinions

Petitioners argue that Special Master Moran's finding that Dr. McCusker's testimony should have greater weight than that of Dr. Axelrod is arbitrary and capricious. Pet. Mem. at 14. Special Master Moran stated in his decision that "[t]he greatest weakness in the Copenhavers' case was the disparity in credentials among the expert witnesses...in immunology." Dec. at 13. Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion. Special Master Moran correctly stated the following:

In considering the value of opinion testimony, special masters may consider the offeror's expertise. *See Snyder v. Sec'y of Health & Human Servs.*, 335 F. Ap'x 994, 1000-02 (Fed. Cir. 2014) (special master's finding that respondent's experts were more persuasive due in part to their current practice in neurology compared to petitioner's expert who had no recent practice was not arbitrary or capricious); *see also, Tompkins v. Sec'y of Health & Human Servs.*, 117 Fed. Cl. 713, 719 (2014) (noting special master reasonably articulated one expert's relative lack of training and experience as a basis for not crediting the witness); *Holmes v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 469, 490 (2014) (stating the special master was reasonable in considering a testifying expert's "research credentials in the field"); *Locane v. Sec'y of Health & Human Servs.*, 99 Fed. Cl. 715, 727 (2011) (finding special master rationally credited an expert with specialization in the disease in determining when the petitioner's disease began), *aff'd*, 685 F.3d 1375, 1380 (Fed. Cir. 2012).

Dec. at 13. Petitioners attempt to argue that, because Dr. Axelrod is "a qualified, actively-practicing immunologist," he and Dr. McCusker should have been afforded similar weight. Pet. Mem. at 17. This Court does not agree.

This case clearly centered on vaccine triggered cytokine expression. Dec. at 14. Dr. Axelrod is a practicing immunologist, but "his knowledge about cytokines appears to stem largely, if not entirely, from reading journal articles. He has not published any articles on cytokines or conducted research on them." Dec. at 17. Dr. McCusker, on the other hand, "practices pediatric immunology every day. She has conducted research on cytokines, and

written several papers on cytokines.” Dec. at 20. Based on the credentials of both experts, Special Master Moran was well within the bounds of his discretion in arriving at the conclusion that Dr. McCusker’s knowledge of cytokines was superior to that of Dr. Axelrod and in affording Dr. McCusker’s testimony greater weight. As such, this Court must uphold those findings as not being arbitrary or capricious.

D. Dr. McCusker’s Expert Testimony

Petitioners further allege that the Special Master erred in allowing Dr. McCusker to testify outside of her field of expertise. Pet. Mem. at 18. The basis of this argument lies in the fact that Dr. McCusker “commented on the work of Dr. Hannah Kinney, who is a neuropathologist, and also commented on other articles pertaining to the neuropathy of SIDS far outside of her field of immunology...Dr. McCusker also offered testimony on how infants breathe, which is far outside of the field of immunology.” Pet. Mem. at 18. While Dr. McCusker may not be an expert in the field of neuropathology, she is a board certified pediatrician. Resp. Ex. D at 3. Special Master Moran determined that “[a]s a board certified pediatrician, Dr. McCusker was much more qualified to explain how infants breathe and what can interfere with respiration than the Copenhavers’ experts, who lacked similar expertise in pediatrics.” Dec. at 22.

Even if petitioners are correct in asserting that Dr. McCusker testified outside of the field her expertise, her testimony is not outcome determinative. The Copenhavers’ theory centers on the idea that vaccination can trigger cytokine expression, which in turn leads to SIDS deaths. *Id.* at 14. Even if Special Master Moran had excluded Dr. McCusker’s testimony involving pediatric respiration, it would not follow that vaccine triggered cytokine expression must be the cause of Nicholas’ death. Dr. McCusker’s testimony may have lent support to the theory that Nicholas’ case involved a respiratory related SIDS death, but, standing alone, her testimony did not, disprove petitioners’ cytokine theory. If Dr. McCusker had not testified about pediatric respiration, petitioners would still have failed to provide, by a preponderance of the evidence, proof that their theory of vaccine triggered cytokine expression was cause of Nicholas’s death. Regardless, Dr. McCusker testified within the bounds of her *pediatric* expertise, and Special Master Moran’s decision to afford her testimony great weight was neither arbitrary nor capricious.

E. The Standard for Burden of Proof

Finally, petitioners allege that the Special Master applied the incorrect standard when determining whether petitioners met their burden of proof. MFR at 2. They argue that Special Master Moran “erroneously required a detailed medical and scientific exposition on the biological mechanisms of Nicholas’ death.” Dec. at 19. Petitioners are correct in their assertion that “[a] finding of causation in fact in vaccine cases can be ‘based on epidemiological evidence and the clinical picture...without detailed medical and scientific exposition on the biological mechanisms.’” *Knudson v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994). In order to succeed in a vaccine claim, petitioners are not required to prove their theory of the

case with scientific certainty. However, petitioners must provide a “reputable medical or scientific explanation.” *Althen*, 418 F.3d at 1278.

This Court is constrained by the Federal Circuit’s decision in *Moberly v. Sec’y of Health & Human Servs.*, which held that “[a]lthough a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” 592 F.3d 1315, 1324 (Fed. Cir. 2010). As previously stated, *Althen* requires that petitioners must provide a “reputable medical or scientific explanation” for their claim.” *Althen*, 418 F.3d at 1278. “The determination of whether a proffered theory of causation is ‘reputable’ may ‘involve an assessment of the relevant scientific data.’” *Hazlehurst ex rel. Hazlehurst v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 473, 479 (2009) (quoting *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009)). Furthermore, “‘reversible error will be extremely difficult to demonstrate’ where the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.’” *Porter*, 663 F.3d at 1253-54 (quoting *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)); *see also Lombardi v. Sec’y of Health & Human Servs.*, 656 F.3d at 1343, 1353 (Fed. Cir. 2010). Such is the case here.

Petitioner’s theory that Nicholas’ July 12, 2013 vaccines may have triggered a cytokine expression that in turn caused his death is not wholly implausible, but “[p]lausibility alone, without medical or scientific support, is not enough to prove a theory of causation.” *Cozart*, 126 Fed. Cl. at 499. Special Master Moran has applied the proper standard in determining whether petitioners met their burden of proof. As a result, we must uphold the Special Master’s decision.

III. CONCLUSION

This Court understands and appreciates the pain inherent in losing a child. Unfortunately, petitioners were unable to meet their burden of proving that Nicholas’ July 12, 2013 vaccinations lead to his untimely SIDS death. For the foregoing reasons, the Court **DENIES** petitioners’ motion for review.¹⁵

IT IS SO ORDERED.

s/ Loren A. Smith

Loren A. Smith,
Senior Judge

¹⁵ This opinion shall be unsealed, as issued, after October 19, 2016, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.